K080497/5 1/3

510(k) Summary
for
Derma Sciences Calcium Alginate Dressing with Antimicrobial Silver

JUN 27 2008

1. COMPANY NAME AND ADDRESS:

Derma Sciences Canada Inc.
104 Shorting Road
Toronto, Ontario M1S 3S4
Canada

Contact Person: Sharmini Atheray
Derma Sciences Canada Inc.
104 Shorting Road
Toronto, Ontario M1S 3S4
Telephone:416-299-4003 x245
Facsimile:416-299-4912

2. DEVICE NAME:

Proprietary Name:	Derma Sciences Calcium Alginate Dressing with Antimicrobial Silver
Common/Usual Name:	Wound dressing
Classification Name:	Dressing

3. PREDICATE DEVICES:

Calcium Alginate Dressing with Antimicrobial Silver (K052536)

4. DEVICE DESCRIPTION:

Calcium Alginate Dressing with Antimicrobial Silver is a primary wound dressing made of Calcium Alginate containing 1.4% Silver. In the presence of wound exudate, the sodium ions from the exudates take the place of the silver ions, releasing the silver ions. As wound exudate is absorbed, the alginate forms a gel, which assist in maintaining a moist environment for optimal wound healing, and allows intact removal. The silver ions released in the presence of wound fluid protect the dressing from bacterial colonisation, and provides an effective barrier to bacterial penetration.

The Derma Sciences Calcium Alginate Dressing with Antimicrobial Silver are sterile, single-use wound care dressings for use in moist wound management. This dressing is offered in several sizes including the following: 2"X2", 4.25"X4.25",4"X5",4"X8",8"X12".

5. INTENDED USE:

For over-the-counter use, Calcium Alginate Dressing with Antimicrobial Silver may be used for:

- abrasions
- minor lacerations
- minor cuts
- minor scalds and burns

Under the supervision of a healthcare professional, Algicell®Ag (Calcium Algiante Dressing with Antimicrobial Silver) dressing is an effective barrier to bacterial penetration in moderate to heavily exuding wound such as:

- diabetic foot ulcer
- leg ulcers (venous stasis ulcers, arterial ulcers and leg ulcers of mixed etiology
- pressure ulcers/sores (partial and full thickness)
- donor sites, and traumatic and surgical wounds.

6. TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

Derma Sciences Calcium Alginate Dressing with Antimicrobial Silver is essentially identical to the device that has been cleared under 510(k) 052536.

Both these devices contain 1.4% silver which is delivered via a sophisticated ionic transfer technology. The net effect is a controlled and sustained release of antimicrobial silver that is effective against infectious pathogens.

Both the dressings are intended as an effective barrier to bacterial penetration for moderate to heavily exudating wounds such as diabetic foot ulcers, leg ulcers (venous stasis ulcers, arterial ulcers and leg ulcers of mixed etiology), pressure ulcers, sores (partial and full thickness), donor sites and traumatic and surgical wounds.

The following modifications have been made to the originally cleared 510k and instructions for use modified accordingly.

- Include *over-the- counter* use claim in addition to the prescription claim.
- Increase the duration of use of the dressing from 5 days to 7 days.

7. PERFORMANCE TESTING

Antimicrobial testing performed to demonstrate successful inhibition of bacteria, yeast and mold at the 7th day (ASTM E2149-01). Cytotoxicity, Sensitization, Skin Irritation Study, Intracutaneous Study, Systemic Toxicity Study and Muscle Implantation study were performed successfully using the Derma Sciences Calcium Alginate Dressing with Antimicrobial Silver.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Derma Sciences Canada, Inc.
% Sharmini Atheray
Corporate Director QA/RA
214 Carnegie Center, Suite 100
Princeton, New Jersey 08540

JUN 27 2008

Re: K080497
Trade/Device Name: Derma Sciences Calcium Alginate Dressing with Antimicrobial Silver
Regulatory Class: Unclassified
Product Code: FRO
Dated: June 18, 2008
Received: June 20, 2008

Dear Sharmini Atheray:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K080497/S1 1/1

FDA U.S. Food and Drug Administration

CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

Indications for Use

510(k) Number (if known): K080497

Device Name: Derma Sciences Calcium Alginate Dressing with Antimicrobial Silver

Indications for Use:

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- abrasions
- minor lacerations
- minor cuts
- minor scalds and burns

Prescription Use _____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use X (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K080497

Indications for Use

510(k) Number (if known): K080497

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(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)